

### **Amendments to the Specification**

Kindly replace the following paragraphs of the specification:

[0012] FIG. 1 The ~~FIGURE~~ depicts a defibrillation system according to an illustrative embodiment of the invention.

FIG. 2A depicts the physiological measuring device 101 according to one embodiment of the invention.

FIG. 2B depicts the physiological measuring device 101 according to another embodiment of the invention.

FIG 3A depicts the data communication channel 124 according to one embodiment of the invention.

FIG 3B depicts the data communication channel 124 according to another embodiment of the invention.

FIG 3C depicts the data communication channel 124 according to another embodiment of the invention.

FIG. 4 is a flow chart illustrative of the steps of one embodiment of the invention.

FIG. 5 is a flow chart illustrative of the steps of one embodiment of the invention.

FIG. 6 is a flow chart illustrative of the steps of one embodiment of the invention.

[0013] The present invention is an alarm system that may be used in a non-medical environment, such as in a home, and is designed to notify a caregiver when a patient requires defibrillation. In an illustrative embodiment, a patient wears a strap preferably containing long-term ECG electrodes 102 such as capacitively-coupled skin electrodes, though standard electrodes with wires leading to a small encased device could alternatively be used. Capacitive electrodes, if desired, can be used for patient comfort, since the patient likely will wear the device for an extended period of time. These electrodes provide a physiological parameter (signal) from the patient, in this illustrative case an ECG. An amplifier 104 raises the ECG level to a point to be compatible with an analog to digital converter 152 connected to or contained in a microprocessor 106. The microprocessor's software includes a ventricular fibrillation detecting

algorithm. Other life-threatening rhythms treatable by a defibrillator may also be detected, but for simplicity these will collectively sometimes be called VF and detectable by a VF detector. Ventricular fibrillation detection algorithms for microprocessors are well known in the art, for example as described in U.S. patent **6,263,238**. Upon occurrence of VF as detected by the microprocessor, an alarm is sounded, alerting someone in proximity to the patient, a so-called caregiver, who then applies an external defibrillator and proceeds to defibrillate.

[0015] Other physiological parameters can be used to sense malignant rhythms. FIG. 2B shows ~~in~~ another embodiment of the physiological parameter measuring device of the invention, a light emitting diode (LED) 155 sends infrared light into the skin while photosensors 156 detect the scattered light. It is well known to those skilled in the art that a waveform proportional to blood flow can be derived from the photosensor in a manner similar to that used in pulse oximeters. See U.S. patent **4,807,630** *for example*. This waveform's pulsatile nature will change when malignant arrhythmias occur and can be used to detect them. Of course the optical method can be used alone or in combination with the ECG or even other physiological parameters. It could be used in a completely patient-worn system or in a system where the detection and alarm function are separated by telemetry as discussed previously.

[0016] Fibrillation detectors, or other physiological parameter, emergency-level detectors, while accurate, are not perfect and the possibility of false alarms must be considered. In another embodiment of the invention, an extra confirming step is added between the fibrillation detector and the alarm function as an emergency level verification system. In this version of the invention, after fibrillation is detected, the signal corresponding to the sensed physiological parameter(s) is sent via communication channel 124 to a remote location such as an off-site central receiving station 116 for human review. The personnel at the receiving center evaluate the physiological data to confirm a malignant rhythm. They then send a confirmation signal to the detector-alarm device enabling the alarm to be activated or they perhaps directly send out an alarm to the caregiver, for example using a pager or cell phone. Communication between the patient's location and the receiving center can be by phone as shown in FIG. 3A or

as in the inventor's U.S. patent **5,966,692** or by other communication means such as the Internet FIG 3B, or other wireless means (FIG. 3C).

[0017] FIG. 1 The FIGURE depicts an illustrative embodiment of a defibrillation system. Box 100 includes illustrative patient-worn components. In FIG. 2A the ECG electrodes 102 provide an analog ECG signal to an amplifier 104. A microprocessor 106 performs an analog to digital conversion on the signal and sends this digitized signal to a radio telemetry transmitter 108. Preferably, the digitized signal is transmitted continuously. Transmitter 108 is preferably a long-range transmitter.

[0021] The basic defibrillation system comprises a physiological parameter measuring device 101, an emergency level detector 151 in communication with the physiological parameter measuring device for detecting emergency level physiological parameters, and a notification device in communication with the emergency level detector 151 for providing notice of the detection of an emergency-level physiological parameter to a caregiver. As used herein a caregiver includes any individual that may respond to a notification such as an alarm or page, and also includes personnel alerted through a central receiving station. A defibrillator is used in conjunction with the defibrillation system and may be sold as part of the system or separately.

[0024] ~~Components of the~~ The defibrillation system may include an emergency level verification system 154 be configured to communicate with a central receiving station. The central receiving station may receive communications from the notification components of the system, directly from the physiological parameter measuring device or from the emergency-level detector. If the signal is received from the physiological parameter measuring device, a determination of emergency levels is performed at the receiving station. It is also possible that the signal from the physiological parameter measuring device is routed to somewhere other than the central receiving station for analysis of whether an emergency-level has been reached, before being routed to the central receiving station. Regardless of which component or components are

in communication with a central receiving station, the receiving station can serve to verify whether defibrillation is needed.

[0026] Embodiments of the defibrillation system may also include stored patient data 153. This data may be available for use for example by the emergency level detection device, the physiological parameter measuring device or the central monitoring station. The system would be configured so the patient data is communicated to the proper system component. The stored patient data 153 may include for example, medical data, patient location data, and emergency contact information.

[0027] The invention also includes a method of using a defibrillator. The method includes measuring a physiological parameter, providing the physiological parameter measurement to an emergency level detector 151, determining if the parameter is at an emergency level, activating a notification device if the physiological parameter is at an emergency level. The notification is received by a caregiver who then utilizes a defibrillator. The methods of the invention include use of components or procedures described herein.